



BRASSICA
PROTECTION PRODUCTS LLC
DEVELOPERS OF CHEMOPROTECTIVE FOODS

December 14, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

**Re: Guidances for Industry: Reducing Microbial Food Safety
Hazards for Sprouted Seeds and Sampling and Microbial
Testing of Spent Irrigation Water During Sprout Production;
Docket Nos. 99D-4488 and 99D-4489**

Dear Sir or Madam:

Brassica Protection Products (BPP) and its carefully selected group of licensed sprout growers applaud the FDA's efforts to improve the safety of green sprouts. The above-noted guidances represent a crucial step in bringing all sprout growers into line with procedures designed to ensure the safety and wholesomeness of sprouts. Indeed, we think it is essential that FDA ensure that these guidelines are followed by all members of the sprout industry.

Background

As the developer of broccoli sprouts, a product we hope will provide significant health benefits, we made food safety a priority well before we marketed our first product. In order to be licensed by BPP, all Brassica growers have been required to practice seed sanitization comparable to the guidelines, have written GMPs, and follow HACCP programs. They will now fully implement FDA's guidance for hold and release testing procedures. The attached letters from Brassica growers indicate their commitment to comply with these guidelines, despite the significant negative financial consequences.

As you may be aware, Brassica officials have met with CFSAN on two occasions to discuss the general HACCP-based principles implemented by its licensed growers. Brassica's procedures include strict criteria for selecting growers; standards for the purchase of seeds; standards for holding seeds; procedures for seed cleaning and treatment at both the supplier and sprouter facility; procedures for monitoring growing conditions; procedures for monitoring harvest and packaging; tracking and enhancing product shelf life; procedures for sprouting room sanitation; and schedules and documentation for environmental microbiological surveying. In many cases, these procedures, which were developed with our partners at Green Giant Fresh and in close collaboration with the Pillsbury company: a) were the first of their kind in this industry, b) were subsequently adopted by the industry trade association (ISGA) for use by all growers and c) have

99D-4488
99D-4489

600 EAST LOMBARD STREET • FIFTH FLOOR • BALTIMORE, MD 21202
TEL: 410-837-9244 • FAX: 410-837-9245 • E-MAIL: MAIL@BRASSICA.COM

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helped to quickly bring the leaders in the sprout industry into line with other fresh vegetable processors.

To date our documentation and sampling data support our view that Brassica products do not present microbial risks to the public. Brassica is currently working in a number of areas, along with our exclusive seed supplier, Caudill Seed Company, to develop and validate new methods that will further enhance consumer safety.

Thus, our practices are consistent with a key element of the agency's guidance: the need for comprehensive, reliable product testing. One cannot espouse an HACCP-based system without agreeing with the necessity of such testing to ensure that HACCP procedures, in fact, are accomplishing the goals they are designed to achieve.

We appreciate the opportunity to comment on the criteria proposed in the guidances and also the agency's recognition that the criteria neither bind producers nor foreclose alternative approaches, provided such approaches result in equivalently safe and wholesome products. We wish to comment on two elements of the guidelines. The first involves the recommended destruction of an entire seed lot based upon a presumptive positive test. The second concerns the reasonableness of testing composite samples rather than individual samples of spent irrigation water.

Seed sanitation and seed lot destruction

Brassica believes that proper seed sanitation is the key to controlling the most prevalent source of contamination. In the context of a properly run GMP program, the most likely source of contamination is seeds. Accordingly, we have chosen to rely on an exclusive seed supplier in order to help ensure that seed delivered to our sprouters is consistently produced within specifications, tested and evaluated. To that end, Caudill Seed practices a HACCP program in its food-grade warehouse, seed lots are regularly tested for pathogens, and there is a strict policy of third party inspections (AIB) on both an announced and unannounced basis.

Nevertheless, seed sanitation is also essential at the sprouting facility. Although it can never be unequivocally proven, it is our belief that contaminated product has never been released to the public from a facility that has properly practiced seed sanitation. In the absence of proof of this, however, we agree with FDA that the hold and release program provides the ultimate protection for the consumer. Brassica continues to work with our growers and industry experts to refine and validate seed sanitation procedures.

We note that any policy that rigidly calls for an entire seed lot to be destroyed based on a presumptive positive test result may well not result in any further reduction in the hazard and runs the risk of creating an unnecessary financial burden. An entire seed lot could represent a enormous portion of a seed supplier's inventory and thus destruction of many thousands of pounds could cause extreme financial hardship. A properly implemented hold and release

program is critical in ensuring a proper balance between public health and economic concerns and fully protects the public from the risk of human pathogen contamination of sprouts.

Since contamination of seed lots may be restricted to a particular bag of seed, and since workplace contamination in the facilities is also a common source of contamination, destroying an entire lot of seed based on a presumptive positive test, or even a confirmed positive test will not increase the level of consumer safety. Additionally, placing the responsibility on the seed supplier may provide a false sense of security for the sprouter, such that they will believe that if the seed is destroyed, the problem may not be in their facility.

What ensures safety here is the hold and release effort, not the destruction of a large amount of seed. Of course, should multiple outbreaks be traced to one seed lot, it will be in the interest of everyone involved, both sprouter and seed supplier, to destroy the entire lot of seed. However, even in this case, a validated hold and release program will ensure that the public health will not be threatened. If a lot of seeds is indeed the culprit, from a pure business standpoint, it will not remain economical to continue with that lot as every contaminated batch will be destroyed under the hold and release program. Therefore, we would argue against any policy that requires an entire seed lot to be destroyed based on one test.

Hold and release, irrigation water sampling

Brassica growers have committed to the proposed hold and release tests in FDA's guidelines. As noted in the attached letters, Brassica growers are fully prepared to destroy batches that are indicated to be contaminated.

What we would ask is that the agency consider allowing flexibility in how these hold and release tests are conducted. Provided the same standards of destroying all product believed to be contaminated are applied, we believe growers should be allowed to test either single batches or to consolidate batches from multiple drums.

Rather than testing each batch of sprouts, a reasonable alternative procedure would be to pool the spent irrigation water samples from a number of batches or drums for testing. The resulting composite sample would then be concentrated at the laboratory. Although pooling samples from multiple batches could be considered to decrease the sensitivity of the assays by diluting the level of pathogens in a contaminated sample, this can be overcome by enhancing the sensitivity of a composite/pooled sample at a qualified testing laboratory. This will maximize the chances that any pathogen will be detected and will, in fact, enhance sensitivity. Should there be a positive test result from the composite, all product represented in the composite would have to be destroyed and every drum included within the composite would be thoroughly broken down, cleaned and sterilized. This required thorough cleaning of the entire processing area would be more likely to destroy any pathogens than just destroying and cleaning one drum. Thus, this protocol places a significant added incentive on the sprouter to carefully sanitize the seed and to

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follow strict growing GMPs, throughout their facility, when compared to the risk of only destroying one drum of product.

Each sprout business will be able to choose a plan that is best tailored to its scale of production. A small grower might want to sample each batch, while a larger grower might find it more palatable to destroy an entire production run after testing composite samples.

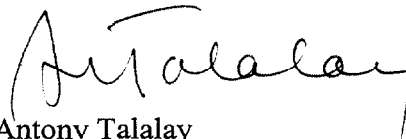
Simply put, producers should be given the opportunity to develop and establish a testing protocol that maintains the sense of the agency's specific guidance, and provides comparable assurance of product safety and integrity, while at the same time permitting a more economically viable alternative approach for producers.

In summary, we thank the FDA for their leadership in this area and for the opportunity to comment on what it is of vital concern to all sprout growers associated with the Brassica mission.

Sincerely,

Handwritten signature of John K. Troyer, with the initials "AMT" written below it.

John K. Troyer, Ph.D.
Laboratory Director

Handwritten signature of Antony Talalay.

Antony Talalay
CEO

Brassica Protection Products LLC

attachments



22 N. Mulberry Street • Lancaster, PA 17603
(717) 392-2707 • Fax: (717) 392-0245

To: John Troyer, Lab Manager
Brassica Protection Products, Inc.

December 8, 1999

Re: Testing Required by FDA Guidelines

Dear John,

I am writing out of concern that the best thing to happen to our industry could turn out to be its death knell. The requirement by the FDA for "hold and release" testing in conjunction with seed sanitation is exactly what is needed to ensure that our products are safe. This is welcomed by those of us who have been doing everything possible to produce safe sprouts.

My concern is with the cost of the testing as currently outlined. The price quotes that we have solicited yield a cost of \$95.00 per drum of sprouts. This cost includes containers for the samples, pickup and testing. The requirements that each sample be from one drum only and for duplicate tests for both pathogens makes the cost prohibitive. Based on average seed yield, I calculate a cost increase of \$.30 per pound. For a 12-4oz. case, this justifies a \$1.00 price increase, which will force retail pricing well over \$1.00 per unit for 4oz. alfalfa, with the actual price depending on the retailer.

At this price level, our products become non-competitive with other fresh green alternatives. Our market has already been damaged by the outbreaks and resulting advisories. A price increase this size will further erode the market and sprout businesses will begin failing.

I would hope that the guidelines could be modified to either allow pooling of samples from up to three drums or to require one test for each pathogen. Costs would then be reduced to a level that would translate into a price increase that would be understood by the trade and the consumer.

Food safety is of paramount importance to the success of our industry, but it must come at a cost which is affordable to the consumer. Please forward my comments to the FDA; we at Sunsprout applaud the approach that FDA has taken and we sincerely believe that there is a middle ground that will ensure food safety at a cost that is affordable.

Sincerely,

A handwritten signature in black ink, appearing to read "Jere Hull".

Jere Hull



To: John Troyer, Laboratory Manager
Brassica Protection Products, Inc.

Re: FDA Testing Guidelines

Dear John,

There are several items of concern in the recent FDA guidelines concerning the microbial testing of sprouts. While we wholeheartedly support the basic idea of testing (and in fact have been doing it for some time now) we feel that some of the specifics of the guidelines are unrealistic and unnecessary.

The requirements dealing with duplicate testing and sampling each drum are cost prohibitive. Our best price quote is \$78.00 per drum not including containers and some delivery. This in itself would require a price increase that is sure to decrease sales in an already shaky market. This also pre-supposes that our sprouts are washed and packaged in single and separate drum lots. This is not the case at all. Sprouts are washed and packaged in seeding lots of normally three drums. Trying to keep drums separate (and emptying and re-sanitizing etc.) would result in an enormous increase in payroll, water, and supplies.

I feel that it only makes sense to modify the guidelines and allow testing on a three drum sample and eliminate redundant testing. We, as sprouters, are also willing to assume the responsibility for the loss and disposal of the entire lot in the event of a positive test. It would seem that the the only risk in a hold for release program is to the sprouter.

Again please let me state that this program is beneficial to those sprouters that have always tried to place food safety at the forefront of their business plan and with some minor modifications in the face of business reality should protect the public and the future of sprouting.

Sincerely,

Bill and Theresa Jones
Sprouters Northwest Inc.

API AMALGAMATED PRODUCE INC.

1318 KOSSUTH STREET BRIDGEPORT, CT 06608
(203) 366-6919 FAX (203) 339-3773

December 8, 1999

TO: JOHN TROYER
FROM: DICK BLACKWELL
RE: FDA GUIDELINES

This is to request a modification in the FDA Guidance that 48-hour water from every growing drum be tested for salmonella and E-Coli 0157, and instead composite testing be conducted, as discussed below:

- Over the past year and a half, extensive testing of API's facility including drains, floors, corners, drums, tables, and product via an outside laboratory, has never shown a positive reading for either one of these pathogens.
- API in its past two inspections by the AIB received an Excellent rating and when we were inspected by the FDA over a two day period, received no corrective action form 483.
- Our outside testing laboratory, Northeast Labs of Berlin, CT (Dr. Ullman), states that the testing process is sensitive enough to detect one pathogenic organism in a composite sample from ten drums.
- API's cost of each test is \$150. If a test is conducted on each of our growing drums this would add approximately \$2 cost to each case of sprouts, which represents an increase of one-third, an amount we cannot absorb and cannot pass along to our consumers. Our business operates on very tight margins already and this cost per drum would destroy API.
- From a sprout safety standpoint, in the very unlikely event that composite testing showed a positive result, we would immediately destroy all implicated inventory, and then conduct an exhaustive test of every drum to determine where the contamination originated. Thus, the bottom line is that the consumer would be protected, but we would also be able to stay in business because the incremental cost of testing would be affordable.





Inc.

303-321-5370

Dockets Management Branch (HFA-305)
5630 Fishers Lane Room 1061
Rockville Md. 20852
RE: Dockets 99D-4488, 99D-4489

4350 GRAPE STREET
UNIT B
DENVER, CO 80216

To Whom it May Concern:

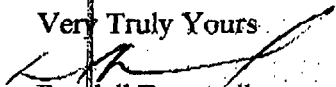
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Being a member of the sprouting industry, I would like to express my concerns in regards to the recently released "Guidance for Industry" pertaining to sprouts.

Although I agree with proper G.M.P.'s, G.A.P.'s a good H.A.A.C.P. program quality facilities and growing equipment along with other protocol and programs to numerous to mention. I must take issue with the Hold and Release program in which sprouters may be required to test spent irrigation water from each drum of product as opposed to pooling samples from all drums during a production run. The cost to run a sample is \$60-\$75 per drum (we opt to also do Listeria along with Salmonella and E-Coli as part of our Food Safety Assurance Program) we run appx. 20 drums per week this cost would be about \$1200-1500 per week, a pooling of drums done twice weekly would be appx. \$120-\$150 per week. Passing the higher number on to the consumer may be too much to bear with the likelihood of pricing us out of business.

Your serious consideration on this issue would be greatly appreciated.

Very Truly Yours


Randall Brownell

Owner Sprouts Ext. L.L.C.

Country Fresh Products, Inc.

2008 W. W. Thorne

Houston, TX 77073

Phone 281-443-8300

Fax 281-443-8880

December 09, 1999

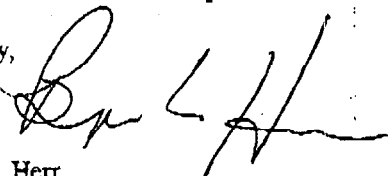
To: F.D.A.

Re: Proposed Sprout Production Regulations

After reviewing the proposed new regulations for safe sprout production, one proposed requirement will totally effect the economics of sprout production. Having to test each drum of sprouts individually would be cost prohibitive. The new chlorine soak and G.M.P.'s have added enough extra costs, but individual testing would cost too much. If we could lump a days production together for testing, we could achieve the same result at a much more economical price.

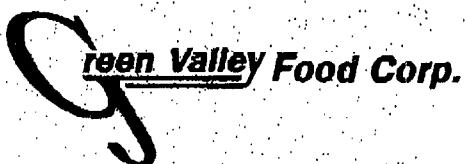
I am definitely in favor of all the new regulations geared to making sprouts a safe product. It won't help any though, if we aren't able to produce economically.

Sincerely,



Bryan C. Herr
President

Organic Fruits, Vegetables, and Specialties



LET'S GROW HEALTHY TOGETHER!

December 9, 1999

To Whom It May Concern,

This letter is in response to the FDA ruling regarding the testing of spent irrigation water. From the beginning we realized the importance of testing all our sprouts. I think any serious sprout grower knows how important it is, both financially and ethically, to have an effective testing program.

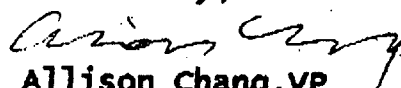
However, as a sprout grower this has caused my production costs to increase dramatically. To be required to test each growing drum is cost prohibitive.

As a responsible grower our company follows all procedures for dis-infection, in addition to buying our seeds only from an approved supplier. Our supplier also has a testing and dis-infection program of their own.

It would be more cost effective just to dispose of a whole sprout harvest, if we had a positive testing, than to test each drum. Therefore, we feel it would be just as effective to pool the spent irrigation water for testing.

On behalf of all the sprout industry we ask the FDA to give this proposal serious consideration.

Yours truly,


Allison Chang, VP
Green Valley Food Corp.

Springwater Sprouts

P.O. Box 406 Honeoye Falls, NY 14472 Tel 716-624-1234 Fax 716-624-1251

December 10, 1999

Mr. John K. Troyer
Brassica Protection Products LCC
600 E. Lombard Ste. 522
Baltimore, MD 21202

Dear John:

In an effort to determine precisely how we should best proceed with the development of a comprehensive program whereby we are sure to be in compliance with the latest FDA guidelines, we have been contacting testing labs both in our immediate area and even some out-of-state. Further, we have been communicating with other growers in various parts of the country to confirm that what we understand as to what should be done is relatively consistent with the direction others are taking.

Parenthetically, one of the things we discovered is that many growers of bean sprouts (solely mung bean and soy bean sprouts) in and around the New York City metropolitan area apparently are not even aware that the new guidelines have been issued.

Against this backdrop, I must confess we are very concerned that unless the guidelines allow for a larger composite pooling of the irrigation water (which we understand many testing labs consider appropriate) the ensuing costs will place the industry in jeopardy, either because the resulting higher retail prices of sprouts will prove prohibitive to the consumer or because the approximate 30% increase in raw costs will prove to be a burden not sustainable for the average grower.

I feel free to say this, John, because as you well know we are in a unique position in our marketing area: i.e., with the exception of some wholesale bean sprout businesses, we are the sole supplier of sprouts in the Western New York area. More importantly, our largest account, Wegmans Food Markets in Rochester, is in a class of its own when it comes to food safety. I'm confident that the FDA will readily acknowledge that Wegmans is in the vanguard of supermarket chains truly focusing on food safety.

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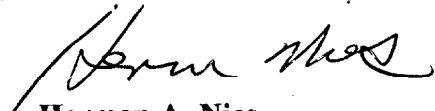
Accordingly, when we sit down with Wegmans to explain our new pricing structure I can guarantee they will not quibble or threaten us with taking their business elsewhere – they have been to our plant often, and they are aware of the stringent measures we have already implemented to be sure our product is safe. What they may say is, “Well, this is all fine and good, but you may be pricing your product out of the reach of many consumers, and you should be prepared for this.” Even then, you can rest assured that they will help us every way they can to get the message out to the consumers that our products *are* safe.

I only hope that we will be permitted to have a larger composite pooling of the irrigation water -- this would blunt many of the problems facing all of us.

Please keep us informed.

Thank you.

Sincerely yours,

A handwritten signature in dark ink, appearing to read 'Herman Nies', written in a cursive style.

Herman A. Nies
Springwater Sprouts